

PATENT
Office No. 1667492021IN THE UNITED STATES PATENT AND TRADEMARK OFFICERespectfully, I, EDWARD L. SINGER

in my official capacity of

Applicant, EDWARD L. SINGER et al.

do hereby declare that

I am the inventor of

the following invention:

Inventor: EDWARD L. SINGERTo: EDWARD L. SINGER et al.
MANUFACTURE AND PHARMACEUTICAL COMPOSITIONS
THEORETICAL

I am submitting this declaration

to the USPTO

in accordance with 35 U.S.C. 115

DECLARATION OF JUDITH A. ROTHMEYER PURSUANT TO 35 U.S.C. 115

I, JUDITH A. ROTHMEYER, do hereby declare that I am the inventor of the following invention:

I am submitting this declaration to the USPTO in accordance with 35 U.S.C. 115. I am submitting this declaration because I am the inventor of the following invention: MANUFACTURE AND PHARMACEUTICAL COMPOSITIONS THEORETICALI am submitting this declaration to the USPTO in accordance with 35 U.S.C. 115. I am submitting this declaration because I am the inventor of the following invention: MANUFACTURE AND PHARMACEUTICAL COMPOSITIONS THEORETICAL

I received my Ph.D. and M.S. degrees in 1989 and 1986, respectively, from the Hebrew University of Jerusalem, Jerusalem, Israel. Since 1991, I have worked for Novartis Pharmaceuticals Corporation, East Hanover, NJ. I am currently the Principal Scientist, Characterization, in the position I am responsible for the physical analysis and characterization of drugs developed by Novartis Pharmaceuticals Corporation. I am responsible for over 15 analysts in the group.

I am aware of the following pending U.S. Patent Applications, which I believe are relevant to the present case:

- (1) Ser. No. 10/630,253 (the '253 application) filed August 27, 2003 and
 - (2) Ser. No. 10/630,254 (the '254 application) filed August 27, 2003 and
 - (3) Ser. No. 10/630,255 (the '255 application) filed August 28, 2003
- concerning the '253, '254 and '255 applications, Novartis Pharmaceuticals Corporation.

I have read and understood the PTO of the applications. Each of these applications was filed as a continuation of a common parent application, Ser. No. 10/152,806, filed May 21, 2002, and the share of the ideal of the invention.

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temperature to cause precipitation. Any change of volume can be replaced by vacuum filtration with stirring for 1/2 hour to the solid and yield. Alternatively, water (optionally cooled to 0-20° C) can be added. Water can be added with stirring of solids within 30 minutes after water addition. Cooling the ethanol solution of azithromycin prior to the addition of water to below below 1-20° C, preferably below 10° C, more preferably below 10, and most preferably 5° C results in substantially pure azithromycin (99.1%). The second form of azithromycin can be collected by filtration and dried.

In Table 5, the chemical formula, molecular weight, formula weight, space group, unit cell dimensions, and other data are given for the

TABLE 5

Crystallographic data of azithromycin form 1

Chemical formula	C ₁₅ H ₁₄ N ₂ O ₆
Formula weight	334.30
Space group	P2 ₁
Unit cell dimensions	a = 1.231 (3) nm b = 0.723 (3) nm c = 0.723 (3) nm

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par 1005.

The term "substantially pure" with reference to a designated crystalline form of a compound means that the designated crystalline form contains less than 1% (by weight) of residual components such as alternate polymorphs or isomeric crystalline forms of a compound. It is preferred that a substantially pure form of a compound contains less than 0.1% (by weight) of the other polymorphs or isomeric crystalline forms of a compound. However, it is preferred that a substantially pure form of a compound contains less than 0.01% (by weight) of the other polymorphs or isomeric crystalline forms of a compound. It is preferred that a substantially pure form of a compound contains less than 0.001% (by weight) of the other polymorphs or isomeric crystalline forms of a compound.

At par 1006, the Pfizer applications state that Form I (and Forms H, J, M, N, O and P) are polymorphs of a compound and have a unit cell of space group $P2_1$ with dimensions $a = 10.412 \text{ \AA}$, $b = 10.412 \text{ \AA}$, and $c = 10.412 \text{ \AA}$. At par 1007, the Pfizer applications state that Form Q (and Forms R, S, T, U, V, W, X, Y, Z, AA, AB, AC, AD, AE, AF, AG, AH, AI, AJ, AK, AL, AM, AN, AO, AP, AQ, AR, AS, AT, AU, AV, AW, AX, AY, AZ, BA, BB, BC, BD, BE, BF, BG, BH, BI, BJ, BK, BL, BM, BN, BO, BP, BQ, BR, BS, BT, BU, BV, BW, BX, BY, BZ, CA, CB, CC, CD, CE, CF, CG, CH, CI, CJ, CK, CL, CM, CN, CO, CP, CQ, CR, CS, CT, CU, CV, CW, CX, CY, CZ, DA, DB, DC, DD, DE, DF, DG, DH, DI, DJ, DK, DL, DM, DN, DO, DP, DQ, DR, DS, DT, DU, DV, DW, DX, DY, DZ, EA, EB, EC, ED, EE, EF, EG, EH, EI, EJ, EK, EL, EM, EN, EO, EP, EQ, ER, ES, ET, EU, EV, EW, EX, EY, EZ, FA, FB, FC, FD, FE, FF, FG, FH, FI, FJ, FK, FL, FM, FN, FO, FP, FQ, FR, FS, FT, FU, FV, FW, FX, FY, FZ, GA, GB, GC, GD, GE, GF, GG, GH, GI, GJ, GK, GL, GM, GN, GO, GP, GQ, GR, GS, GT, GU, GV, GW, GX, GY, GZ, HA, HB, HC, HD, HE, HF, HG, HH, HI, HJ, HK, HL, HM, HN, HO, HP, HQ, HR, HS, HT, HU, HV, HW, HX, HY, HZ, IA, IB, IC, ID, IE, IF, IG, IH, II, IJ, IK, IL, IM, IN, IO, IP, IQ, IR, IS, IT, IU, IV, IW, IX, IY, IZ, JA, JB, JC, JD, JE, JF, JG, JH, JI, JJ, JK, JL, JM, JN, JO, JP, JQ, JR, JS, JT, JU, JV, JW, JX, JY, JZ, KA, KB, KC, KD, KE, KF, KG, KH, KI, KJ, KK, KL, KM, KN, KO, KP, KQ, KR, KS, KT, KU, KV, KW, KX, KY, KZ, LA, LB, LC, LD, LE, LF, LG, LH, LI, LJ, LK, LL, LM, LN, LO, LP, LQ, LR, LS, LT, LU, LV, LW, LX, LY, LZ, MA, MB, MC, MD, ME, MF, MG, MH, MI, MJ, MK, ML, MM, MN, MO, MP, MQ, MR, MS, MT, MU, MV, MW, MX, MY, MZ, NA, NB, NC, ND, NE, NF, NG, NH, NI, NJ, NK, NL, NM, NN, NO, NP, NQ, NR, NS, NT, NU, NV, NW, NX, NY, NZ, OA, OB, OC, OD, OE, OF, OG, OH, OI, OJ, OK, OL, OM, ON, OO, OP, OQ, OR, OS, OT, OU, OV, OW, OX, OY, OZ, PA, PB, PC, PD, PE, PF, PG, PH, PI, PJ, PK, PL, PM, PN, PO, PP, PQ, PR, PS, PT, PU, PV, PW, PX, PY, PZ, QA, QB, QC, QD, QE, QF, QG, QH, QI, QJ, QK, QL, QM, QN, QO, QP, QQ, QR, QS, QT, QU, QV, QW, QX, QY, QZ, RA, RB, RC, RD, RE, RF, RG, RH, RI, RJ, RK, RL, RM, RN, RO, RP, RQ, RR, RS, RT, RU, RV, RW, RX, RY, RZ, SA, SB, SC, SD, SE, SF, SG, SH, SI, SJ, SK, SL, SM, SN, SO, SP, SQ, SR, SS, ST, SU, SV, SW, SX, SY, SZ, TA, TB, TC, TD, TE, TF, TG, TH, TI, TJ, TK, TL, TM, TN, TO, TP, TQ, TR, TS, TT, TU, TV, TW, TX, TY, TZ, UA, UB, UC, UD, UE, UF, UG, UH, UI, UJ, UK, UL, UM, UN, UO, UP, UQ, UR, US, UT, UY, UZ, VA, VB, VC, VD, VE, VF, VG, VH, VI, VJ, VK, VL, VM, VN, VO, VP, VQ, VR, VS, VT, VU, VV, VW, VX, VY, VZ, WA, WB, WC, WD, WE, WF, WG, WH, WI, WJ, WK, WL, WM, WN, WO, WP, WQ, WR, WS, WT, WU, WV, WW, WX, WY, WZ, XA, XB, XC, XD, XE, XF, XG, XH, XI, XJ, XK, XL, XM, XN, XO, XP, XQ, XR, XS, XT, XU, XV, XW, XX, XY, XZ, YA, YB, YC, YD, YE, YF, YG, YH, YI, YJ, YK, YL, YM, YN, YO, YP, YQ, YR, YS, YT, YU, YV, YW, YX, YY, YZ, ZA, ZB, ZC, ZD, ZE, ZF, ZG, ZH, ZI, ZJ, ZK, ZL, ZM, ZN, ZO, ZP, ZQ, ZR, ZS, ZT, ZU, ZV, ZW, ZX, ZY, ZZ.

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